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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Joseph L. Duffy, et al

Serial No.

10/540.283

Filed: June 20, 2005

For: 3-AMINO-4-PHENYLBUTANOIC ACID DERIVATIVES

AS DIPEPTIDYL PEPTIDASE INHIBITORS FOR THE TREATMENT OR PREVENTION OF DIABETES

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Art Unit: To Be Assigned

Examiner: <u>To Be Assigend</u>

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

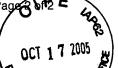
Sir:

- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
- 4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Neur & Mon



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5. Pursuant 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited

by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120

are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

	RELATED APPLICATION			
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE		
10/530,215	April 4, 2005	21239YP		
0/537,476	June 3, 2005	21288YP		
If this is inconvenient, additional copies will be submitted up	oon request.			
6. In accordance with 37 C.F.R. 1.97, (check one)				
the attached information is filed within three months of t	he filing date of the captioned case			
the attached information is filed more than three months Office Action on the merits.	s after the filing date but prior to the	mailing of a first		
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the attached information is being filed more than three no Office Action on the merits, but before the mailing date of otherwise closes prosecution in the application. The en Account No. 13-2755 for the fee required under 37 C.F.	of a Final Action, Notice of Allowan closed authorization is therefore gi	ce, or an action that		
each item of information contained in this Information D from a foreign patent office in a counterpart foreign appl Statement.				
each item of information contained in the information dis a foreign patent office in a counterpart application and t designated in §1.56(c) more than thirty days prior to the	this communication was not receive	ed by any individual		
no item of information contained in this Information Disc foreign patent office in a counterpart foreign application, after making reasonable inquiry, was known to any indiv months prior to the filing of this Statement.	, and, to the knowledge of the perso	on signing the certification		
	Respectfully submitted,			
	(Solone < C	wette		
				
	By: Philippe L. Durette			
	Attorney For A	pplicant(s)		
	Attorney For A Reg. No. 35,125			
	Attorney For A Reg. No. 35,125 MERCK & CO., INC.			
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	Attorney For A Reg. No. 35,125 MERCK & CO., INC. Patent Dept., RY60-30 P.O. Box 2000	pplicant(s)		

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•		INFOR	MATION I	DIS	SURE	Application Number	10/54			
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	STATEMENT BY APPLICANT				FLICANI	First Named Inventor	Joseph L. Duffy, et al.			
2	OCT 1	7 2005	.			Group Art Unit				
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U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.	U.S. Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
	1	6,699,871 B2		Edmondson et al.	03/02/2004		
	2	6,011,155		Villhauer	01/04/2000		
	3	6,166,063		Villhauer	12/26/2000		
	4	5,939,560		Jenkins et al.	08/17/1999		
	5	6,303,661 B1		Demuth et al.	10/16/2001		
	6	6,432,969 B1		Villhauer	08/13/2002		
	7	4,386,090		Moinet et al	05/31/1983		
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	FOREIGN PATENT DOCUMENTS							
			Foreign Patent Document			Date of Publication of		
Examiner Initials*	Cite No.	Office	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY		
	8	PCT	WO 03/082817 A2		MERCK & CO., INC.	10/09/2003		
	9	PCT	WO 03/000180 A2		MERCK & CO., INC.	01/03/2003		
	10	PCT	WO 03/000181 A2		MERCK & CO., INC.	01/03/2003		
	11	PCT	WO 03/000181 A3		MERCK & CO., INC.	01/03/2003		
	12	PCT	WO 02/076450 A1		MERCK & CO., INC.	10/03/2002		
	13	PCT	WO 2004/007468 A1		MERCK & CO., INC.	01/22/2004		
	14	PCT	WO 2004/032836 A2		MERCK & CO., INC.	04/22/2004		
	15	PCT	WO 2004/050022 A2		MERCK & CO., INC.	06/17/2004		
	16	PCT	WO 2004/058266 A1		MERCK & CO., INC.	07/15/2004		
	17	PCT	WO 2004/064778 A2		MERCK & CO., INC.	08/05/2004		

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1	Substitute for form 1449A/PTO		COMPLETE IF KNOWN
ı	INFORMATION DISCOSURE	Application Number	10/5 3
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1	6 PSTATEMENT BY APPLICANT	First Named Inventor	Joseph L. Duffy, et al.
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U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.	U.S. Patent Document			Date of Publication of Cited Document MM-DD-YYYY		
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			FOREI	GN PATEN	T DOCUMENTS	
Examiner Cite Initials* No.		Foreign Patent Document Office Number K			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	18	PCT	WO 2004/069162 A2	(if known)	MERCK & CO., INC.	08/19/2004
	19	PCT	WO 02/02560 A2		NOVO NORDISK A/S	01/10/2002
	20	PCT	WO 01/96295 A2		NOVARTIS AG	12/20/2001
	21	PCT	WO 01/96295 A3		NOVARTIS AG	12/20/2001
	22	PCT	WO 01/34594 A1		Guilford Pharmaceuticals, Inc.	05/17/2001
	23	PCT	WO 00/34241		NOVARTIS AG	06/15/2000
	24	PCT	WO 98/19998 A2		NOVARTIS AG	05/14/1998
	25	PCT	WO 98/19998 A3		NOVARTIS AG	05/14/1998
	26	PCT	WO 97/40832		Hansknoll-Institut Fur Naturstoff-Forschung E.V.	11/06/1997
	27	PCT	WO 03/000180 A3		MERCK & CO., INC.	01/03/2003

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	ENFORMATIO	N DIS	OSURE	Application Number	10/54
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	7 2005 E	DI AFFI	ICANI	First Named Inventor	Joseph L. Duffy, et al.
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She		of	4	Attorney Docket Number	21304YP
		1 1	4	Attorney Docket Number	21304YP

			U.S. PATE	NT DOCUMENTS	
Examiner Initials*	Cite No.	U.S. Patent Docum	U.S. Patent Document Name of Patentee or Applicant		Date of Publication of Cited Document MM-DD-YYYY
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	FOREIGN PATENT DOCUMENTS							
Examiner Cite Initials* No.		Foreign Patent Document Office Number			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
	28	PCT	WO 02/02560	(if known) A3	NOVO NORDISK	01/10/2002		
-	29	PCT	WO 01/42262		AKZO NOBEL N.V.	06/14/2001		
	30	PCT	WO 2004/043940		MERCK & CO., INC.	05/27/2004		
	31	PCT	WO 2004/007468		MERCK & CO., INC.	01/22/2004		
	32	PCT	WO 2004/110436		MERCK & CO., INC.	12/23/2004		
	33	PCT	WO 2004/112701	A2	MERCK & CO., INC.	12/29/2004		
	34	PCT	WO 2004/112701	A3	MERCK & CO., INC.	12/29/2004		
	35	РСТ	WO 2005/011581	A2	MERCK & CO., INC.	02/10/2005		
	36	PCT	WO 2005/044195	. A2	MERCK & CO., INC.	05/19/2005		
	37	PCT	WO 2005/002530	· A2	SMITHKLINE BEECHAM CORP.	01/09/2003		

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	• <u> </u>				Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE	
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•	INFORMATION D	IŠ.	OSURE	Application Number	10/5 3	
6	OCI 17 2007 (use is many sheets as necessary)			Filing Date	June 3, 2005	
				First Named Inventor	Joseph L. Duffy, et al.	
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	NON PATENT LITERATURE DOCUMENTS								
Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.								
38	J. J. Holst, "Treatment of Type 2 Diabetes Mellitus with Agonists of the GLP-1 Receptor or DPP-IV Inhibitors", Expert Opin. Emerg. Drugs, Vol. 9(1) pp. 155-166, 2004.								
39	C. F. Deacon, et al., "Inhibitors of dipeptidyl peptidase IV: A Novel Approach for the Prevention and Treatment of Type 2 Diabetes?", Expert Opin. Investig. Drugs, Vol. 13(9) pp. 1091-1102, 2004.								
40	K. Augustyns et al., "Dipeptidyl Peptidase IV Inhibitors as New Therapeutic Agents for the Treatment of Type 2 Diabetes", Expert Opin. Ther. Patents, Vol. 13(4), pp. 499-510, 2003.								
41	Novartis AG: WO0034241, "Novel N-substituted-2-Cyanopyrrolidines as Potent Inhibitors of Dipeptidyl Peptidase IV in the Treatment of Non-Insulin-Dependent Diabetes Mellitus", Exp. Opin. Ther. Patents, Vol. 10(12), pp. 1937-1942, 2000.								
42	O. J. Orucker, "Therapeutic potential of dipeptidyl peptidase IV inhibitors for the treatment of type 2 diabetes", Exp. Opin Invest. Drugs, Vol.12, 2004, pages 87-100.								
43	T. P. Vahl & D. A. D'Alessio, "Gut peptides in the treatment of diabetes mellitus" Exp. Opin. Invest. Drugs, Vol. 13, 2004, pages 177-188.								
44	L. B. Knudsen, "Glucagon-like peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes", J. Med. Chem, Vol. 47, 2004, pages 4128-4134.								
45	Ann E. Weber, "Dipeptidyl Peptidase IV Inhibitors for the Treatment of Diabetes", J. Med. Chem, Vol. 47, 2004, pages 4135-4141.								
46	J. J. Holst and C. F. Deacon, "Glucagon-like peptide 1 and inhibitors of dipeptidyl peptidase IV in the treatment of type 2 diabetes mellitus", Curr. Opin Pharmacology, Vol. 4, 2004, pages 589-596.								
47	C. F. Deacon, "Perspectives in Diabetes - Therapeutic Strategies Based on Glucagon-Like Peptide 1", Diabetes, Vol. 53, Sept. 2004, pages 2181-2189.								
	No. 38 39 40 41 42 43 44 45 46								

Examiner Signature		Date Considered	

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